AMENDMENT TO COMMITTEE PRINT

OFFERED BY MR. MARKEY OF MASSACHUSETTS

[(REMS_003; June 19, 2007)

Amend section 5 (page 51, line 1 through page 66, line 4) to read as follows:

SEC. 5. POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM FOR ACTIVE SURVEILLANCE AND ASSESSMENT.

(a) FINDINGS.—Congress finds the following:

(1) It is in the best interests of healthcare providers and patients that a postmarketing surveillance system be developed that will enable active surveillance of disparate sources of data to identify signals of unexpected adverse events and trends in the frequency of known adverse events, to provide data on the outcomes of off label uses, and to enable identification of safety issues earlier than can be done today.

(2) Such a system can best be developed through public private partnerships to develop methods and tools for conducting surveillance using electronic databases that currently contain data on millions of patient encounters and are expected to grow

significantly in the next decade, as well as electronic databases that contain millions of medical product purchases, health care claims, and similar information relevant to product use, efficacy, and safety.

(3) Therefore, this section directs the Secretary of Health and Human Services to enter into such public private partnerships as are necessary to develop such a surveillance system and the tools and methods necessary to conduct active surveillance using the system.

(b) DEVELOPMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—Subsection (k) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

"(3) The Secretary shall establish public private partnerships to develop tools and methods to enable the Secretary and others to use available electronic databases to create a robust surveillance system that will support active surveillance on important drug safety questions including detecting and assessing drug safety signals; monitoring the frequency of known adverse events; and evaluating the outcomes of off label uses. Such surveillance shall provide for adverse event surveillance using the following data sources:

"(A) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs).

"(B) Private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data).

"(C) Other information as the Secretary deems useful to create a robust system to identify and assess adverse events and potential drug safety signals and to evaluate the extent and outcomes of off label uses of drugs.

"(4) Not later than 1 year after the date of the enactment of [REMS], the Secretary, in consultation with experts including individuals who are recognized in the field of data privacy and security, shall develop methods for integrating and analyzing safety data from multiple sources and mechanisms for obtaining access to such data. Such methods and mechanisms shall not compromise the protection of individually identifiable health information.

"(5) Not later than 2 years after the date of the enactment of [REMS], the Secretary shall have entered into partnerships that will allow the analysis of available data from the various data sources using the standards and methods to identify drug safety signals and trends. Such

analysis shall not disclose individually identifiable health information when presenting such drug safety signals and trends or when responding to inquiries regarding such drug safety signals and trends.

"(6) Not later than 4 years after the date of the enactment of [REMS], the Secretary shall report to the Congress on the ways in which the Secretary has used the surveillance system described in this subsection to identify specific drug safety signals and to better understand the outcomes associated with drugs marketed in the United States.

"(7) Disclosure of individually identifiable information is prohibited in the surveillance system described in this subsection. Nothing in this subsection prohibits lawful disclosure of such information for other purposes.

"(8) Nothing in this subsection shall be construed as limiting public health activities authorized under law."

(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out activities under the amendment made by subsection (b) for which funds are made available under section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), there are authorized to be appropriated to carry out such amendment made by this section, in addition to such funds, $25,000,000 for each of fiscal years 2008 through 2012.

(d) GAO REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall evaluate data confidentiality and security issues relating to collection, transmission, and maintenance of data for the surveillance system developed pursuant to this section, and make recommendations to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate, and any other Congressional committees of relevant jurisdiction, regarding the need for any additional legislative or regulatory actions to ensure confidentiality and security of this data or otherwise address confidentiality and security issues to ensure the effective operation of the surveillance system.